

# MEMORANDUM



## DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service Food and Drug Administration Center for Drug Evaluation and Research

DATE: December 21, 2005

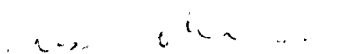
FROM: Acting Director  
Division of Nonprescription Regulation Development  
Office of Nonprescription Products

SUBJECT: Public Administrative File for Over-the-Counter Phenylpropanolamine-Containing Drug Products; Tentative Final Monograph (Docket No. 1981N-0022)

TO: Division of Dockets Management (HFA-350)

Under cover of this memorandum, we are forwarding Volume No. 17PPATFM to be added to the public administrative file for the Tentative Final Monograph for Phenylpropanolamine-Containing Drug Products for Over-the-Counter Human Use. The volume includes new references cited in the tentative final monograph that are not currently included in the public administrative file.

If there are any questions, the contact person on my staff is Robert Sherman at 301-796-0996.

  
Susan S. Johnson, Ph.D.

1981N-0022

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## References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. LET86, Docket No. 81N-0022.
2. Horwitz et al., "Phenylpropanolamine & Risk of Hemorrhagic Stroke: Final Report of The Hemorrhagic Stroke Project," May 10, 2000 in Comment No. C230, Docket No. 76N-052N and Comment No. RPT14, Docket No. 81N-0022.
3. Phenylpropanolamine case reports from 1991 to 2000 on file in Docket Nos. 76N-052N and 81N-0022.
4. Consumer Healthcare Products Association (CHPA), "Comments on the Hemorrhagic Stroke Project Report," May 24, 2000, in Comment No. C231, Docket No. 76N-052N and Comment No. C113, Docket No. 81N-0022.
5. Food and Drug Administration, Transcript of Nonprescription Drugs Advisory Committee meeting, October 19, 2000, in Docket Nos. 76N-052N and 81N-0022.
6. Food and Drug Administration, Public Health Advisory. "Safety of Phenylpropanolamine," November 6, 2000. Comment No. M1 in Docket No. 76N-052N and Comment No. M7 in Docket No. 81N-0022.
7. Office of Management and Budget, "Guidelines to Standardized Measures of Costs and Benefits and the Format of Accounting Statements," M0008, March 22, 2000, downloaded from <http://www.whitehouse.gov/omb/memoranda/index.html>, accessed June, 13, 2001.
8. Jarvis, Lisa, "PPA Ban Is a Serious Threat to OTC Diet Aids." Chemical Market Reporter, November 20, 2000.
9. Security and Exchange Commission, Form 10K-405, American Homes Products Corp., downloaded from <http://www.sec.gov/archives/edgar/data>, accessed June 13, 2001.
10. F-D-C Reports-"The Tan Sheet," "Dexatrim Natural Fattens Chattem's First Quarter; Extensions Planned," vol. 9, no. 14, April 2, 2001.
11. F-D-C Reports-"The Tan Sheet," "AHP Dimetapp, Robitussin PPA Withdrawals Lead To \$80 Mil. Charge In 2000," vol. 9, no. 5, January 29, 2001.
12. Taylor, Thomas N., "The Medical Economics of Stroke," Drugs, supp. 3:51-58, 1997.

13. U.S. Census Bureau, No. 768, Consumer Price Index by Major Group., downloaded from <http://www.census.gov.statab>, accessed June 12, 2001. U.S. Bureau of Labor Statistics, Series CURROOOOSAM, EXTRACTED July 23, 2004. Updated 1999 data to 2003 (18.56 percent increase in medical care CPI).

14. Kernan, Walter N. et al., "Phenylpropanolamine and the Risk of Hemorrhagic Stroke," The New England Journal of Medicine, 343: 1826-1832, 2000.

15. Fisher, A., L., G. Chestnut, and D. M. Violette, "The Value of Reducing Risks of Death: a Note on New Evidence," Journal of Policy Analysis and Management, 8: 88-100, 1989